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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,068	08/01/2001	Eckhard Wolf	50125/015002	4409

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EXAMINER
CHEN, LIPING

ART UNIT	PAPER NUMBER
1632	9

DATE MAILED: 09/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/920,068	Applicant(s) WOLF ET AL.	
	Examiner Liping Chen	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to a G-protein-coupled receptor-polypeptide, classified in 530, subclass 350^{+}.

II. Claims 3-6 and 17, drawn to nucleic acid, a cell and a method of producing a polypeptide, classified in 435, subclass 69.1.

III. Claims 7, 8 and 18, drawn to a transgenic embryonic non-human stem cell, a transgenic non-human mammal, and a method of making, classified in class 800, subclass 13.

IV. Claims 9 and 19, drawn to an antibody or antibody fragment and a method of making, classified in 424, subclass 130.1^{+}.

V. Claims 10, 11, 22, 25-27, 33, and 34, drawn to a test, which contains at least one G-protein-coupled receptor-polypeptide, for identification of pharmacologically active substance, a method of using the test, classified in class 530, subclass 350+.

VI. Claims 10, 11, 22, 25-27, 29, 33, and 34, drawn to a test, which contains at least one nucleic acid encoding the G-protein-coupled receptor-polypeptide, for identification of pharmacologically active substance, a method of using the test, and a method of using, classified in class 435, subclass 6.

VII. Claims 10, 11, 22, 25-27, 33, and 34, drawn to a test, which contains at least one antibody directed against the G-protein-coupled receptor-polypeptide, for identification of pharmacologically active substance, a method of using the test, and a method of using, classified in class 435, subclass 7.1+.

VIII. Claims 10, 11, 22, 25-27, 30, 33, and 34, drawn to a test, which contains at least one cell expressing the G-protein-coupled receptor-polypeptide, for identification of pharmacologically active substance, a method of using the test, and a method of using, classified in class 435, subclass 4.

IX. Claims 10, 11, 22, 33, and 34, drawn to a test, which contains at least one transgenic non-human mammal containing the nucleic acid encoding the G-protein-coupled receptor-polypeptide, for identification of pharmacologically active substance, a method of using the test, and a method of using, classified in class 800, subclass 3.

X. Claims 12, 21 and 23, 28, 33 and 34, drawn to an array, which contains at least one G-protein-coupled receptor-polypeptide, fixated to a carrier material, a method of producing the array, and a method of using, classified in class 422, subclass 68.1.

XI. Claims 12, 21 and 23, 28, 29, 33 and 34, drawn to an array, which contains at least one nucleic acid encoding the G-protein-coupled receptor-polypeptide, fixated to a carrier material, a method of producing the array, and a method of using, classified in class 422, subclass 68.1.

XII. Claims 12, 21 and 23, 28, 33 and 34, drawn to an array, which contains at least one antibody directed against the G-protein-coupled receptor-polypeptide, fixated to a carrier material, a method of producing the array, and a method of using, classified in class 422, subclass 68.1.

XIII. Claims 12, 21 and 23, 28, 30, 33 and 34, drawn to an array, which contains at least one cell expressing the G-protein-coupled receptor-polypeptide, fixated to a carrier material, a method of producing the array, and a method of using, classified in class 422, subclass 68.1.

XIV. Claims 13, 14, 20 and 24, drawn to a diagnostic, which contains at least one G-protein-coupled receptor-polypeptide, and a method of producing, classified in class 530, subclass 350+.

XV. Claims 13, 14, 20, 24 and 29, drawn to a diagnostic, which contains at least one nucleic acid encoding the G-protein-coupled receptor-polypeptide, and a method of producing, classified in class 536, subclass 23.1.

XVI. Claims 13, 14, 20 and 24, drawn to a diagnostic, which contains at least antibody directed against the G-protein-coupled receptor-polypeptide, and a method of producing, classified in class 530, subclass 387.1+.

XVII. Claims 13, 14, 20, 24 and 30, drawn to a diagnostic, which contains at least one cell expressing the G-protein-coupled receptor-polypeptide, and a method of producing, classified in class 435, subclass 325+.

XVIII. Claims 15, 16 and 20, 24, 33 and 34, drawn to a pharmaceutical containing at least one G-protein-coupled receptor-polypeptide, a method of producing, and a method of using, classified in class 514, subclass 2.

XIX. Claims 15, 16 and 20, 24, 33 and 34, drawn to a pharmaceutical containing at least one nucleic acid encoding the G-protein-coupled receptor-polypeptide, a method of producing, and a method of using, classified in class 514, subclass 44.

XX. Claims 15, 16 and 20, 24, 33 and 34, drawn to a pharmaceutical containing at least one antibody directed against the G-protein-coupled receptor-polypeptide, a method of producing, and a method of using, classified in class 424, subclass 130+.

XXI. Claims 15, 16 and 20, 24, 33 and 34, drawn to a pharmaceutical containing at least one cell expressing G-protein-coupled receptor-polypeptide, a method of producing, and a method of using, classified in class 424, subclass 93.1.

XXII. Claims 31, 33 and 34, drawn to a method of using pharmacologically active substances such as organic compound, which is identified by a G-protein-coupled receptor-polypeptide or a related nucleic acid, an antibody or a cell, for manufacture of a pharmaceutical, where at least one pharmacologically active substances is combined with suitable auxiliaries and/or additives, classified in class 514, subclass 1.

XXIII. Claim 32-34, drawn to a method of using pharmacologically active substances such as organic compound, which is identified by a G-protein-coupled receptor-polypeptide or a

related nucleic acid, an antibody or a cell, for diagnosis, prevention or treatment of diseases, classified in class 514, subclass 1.

The inventions are distinct, each from the other because:

Groups I-IV are distinct from each other because they are drawn to compositions with different classification: polypeptide, nucleic acid, non-human transgenic animal and antibody, respectively. These compositions have different chemical structures, physical properties and biological functions, and requiring separate search. Search for polypeptide does not require search for nucleic acid, non-human transgenic animal, or antibody, search for nucleic acid does not require search for polypeptide, non-human transgenic animal, or antibody, and search for non-human transgenic animal does not require search for, polypeptide, nucleic acid, or antibody. Since the classification for each is different, the search for each group would not be coextensive. They are not obvious variants and deemed patentably distinct.

Groups V-IX are distinct from each other because they are drawn to methods using different compositions for test, having different chemical structures, physical properties and biological functions, and requiring separate search, they are: polypeptide, nucleic acid, antibody, cell and non-human transgenic mammal, respectively. They are methods that differ at least in reagents used, doses and schedules used, response variables, and criteria of success. Since the classification for each is different, the search for each group would not be coextensive. They are patentably distinct.

Groups X-XIII, drawn to an array. They are distinct from each other because they are drawn to using different compositions for array: polypeptide, nucleic acid, antibody, and cell, respectively. The reasoning as indicated above (Group I-V). Since the classification for each is different, the search for each group would not be coextensive. They are patentably distinct.

Groups XIV-XVII, drawn to a diagnostic. They are distinct from each other because they are drawn to using different compositions for diagnostic: polypeptide, nucleic acid, antibody, and cell, respectively. The reasoning as indicated above (Group I-V). Since the classification for each is different, the search for each group would not be coextensive. They are patentably distinct.

Groups XVIII-XXI, drawn to a pharmaceutical. They are distinct from each other because they are drawn to using different compositions for array: polypeptide, nucleic acid, antibody, and cell, respectively. The reasoning as indicated above (Group I-V). Since the classification for each is different, the search for each group would not be coextensive. They are patentably distinct.

Groups XXII and XXIII are distinct from each other because Group XXII drawn to a method for manufacture of a pharmaceutical, whereas Group XXIII drawn to a method of a method for treatment. They are methods that differ at least in reagents used, doses and schedules used, response variables, and criteria of success. The method used for one invention is not needed for implementation of another invention, and vise versa. Each of the methods requires a separate and materially different protocol.

Group I and any one of groups V, X, XIV or XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of group I can be used for antibody production.

Group II and any one of groups VI, XI, XV or XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group II can be used for protein production in vitro.

Group III and any one of Groups VII, XII, XVI, or XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic non-human mammal of group III can be used as disease model.

Group IV and any one of Groups VIII, XIII, XVII, or XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of group IV can be used for immunoprecipitation.

A test of groups V-IX, an array of groups X-XIII, a diagnostic of groups XIV-XVII, a pharmaceutical of groups XVIII-XXI, a method of using pharmaceutically active substances for manufacture of groups XXII and a method of using pharmaceutically active substances for treatment of groups XXIII, each are mutually exclusive and independent from others. They are methods that differ at least in reagents used, doses and schedules used, response variables, and criteria of success. The method used for each of the group is not needed for implementation of other groups, and vise versa. Each of the methods requires a separate and materially different protocol.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, because of their recognized divergent subject matter, and the search required for any group is not required for remaining groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liping Chen, whose telephone number is (703) 305-4842. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time). Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Pauline Farrier, Patent Analyst, at (703) 305-3550. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

Liping Chen, Ph.D.
Patent Examiner
Group 1632
September 16, 2002

SHIN-LIN CHEN
PATENT EXAMINER